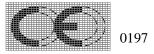


Standard No. YZB/沪 0415-10-2012



Medical electric saw drill

Technical operating manual

Shanghai Bojin Medical Instrument Co.,Ltd.

Address: A Zone of F2,C Zone of F1,No.125,Longpan Road,Jiading District,Shanghai,China

Post code: 201800 Tel: 0086-21-39908516 Fax:0086-21-39908016

Date: 2017-08-15

Medical electric saw drill

Usage and feature:

Medical electrical saw drill is the new product designed by our company for surgery operation. The instrument has the beautiful figure, small volume, light weight, without the electrical wire, easily to be carried and safely operating, so it can reduce the operating time.

Composition:

The electrical saw drill is composed of main unit, charger and battery. Or it also can be composed of charger, battery, main unit and the spare parts. All the shells are completely sealed. The charger doesn't classified as medical instrument.

Model explanation

| Model | Composition | |
|----------|---|--|
| BYJZ – 1 | Main unit, saw, drill, charger, battery | |
| BYJ – 1 | Main unit, saw, charger, battery | |
| BYZ - 1 | Main unit, saw, charger, battery | |

Main technical feature:

Main unit:

working voltage: 14.4V Output power: ≥100W

Charger:

Input voltage: AC 220V, 50Hz

Output voltage: 14.4V

Charging time: About 3 Hours

Input power: 30VA

Battery:

Voltage: 14.4V

Technical data:

Saw non-load frequency: ≥6000 times/min

Non-load noise: $\leq 70db(A)$

Products classification:

Medical electric saw drill's classification accords with the protection, the motor belongs to inner power B type device, charger belongs to II - B type common device; the device can not be used in flammable anaesthesia air & air mix or oxygen mix air.

Complementarily marking

Duty: Intermission load run continuously. Start up from the cool situation, run for 5 minutes under the full load, make it cool then repeat the above situation.

Label explanation:

1

EC | REP Bojin Italia di Maurizio Marra Via Ortana 20, 01030 Vitorchiano VT-Italy

This figure on the label shows the name and the address of the EU domestic authorized representative.



0197

This figure on label shows that this device is hereinafter confirmed to comply with the requirements set out in the Council Directive

on the harmonization of the Laws of the Member States concerning Medical Device Directive(93/42/EEC As amended by 2007/47/EC)



Separate collection for electrical and electronic equipment

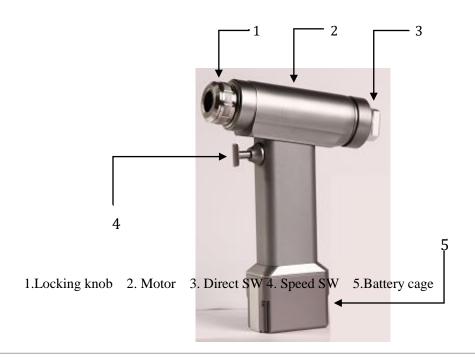
Rotating mark: L: CW R: CCW

Explanation:

The product is the professional medical instrument, the user must be the person who has the relative technical experience or has been trained.

The product should be used after disinfecting, the product should be test before normal usage, the method: insert the battery to the main unit, press the switch lightly then the motor should be rotating, exchange the CW/CCW switch, the motor should be running, otherwise the main unit has malfunction, so stop using immediately and contact to the seller, mail the instrument to the factory to repair.

BYJZ – I Handpiece:



Technical data:

High-speed drill: ≥801--1500r/min

Low-speed drill:100--450r/min

Oscillating saw Frequency:6000b/min

Middle-speed drill:451--800r/min

Drilling and milling tools: ≥12000r/min

Reciprocating saws: ≥6000b/min

1. Installation and removal of the saw blade

According to the figure downward pressure lock button, insert the blade into the turret, then loosen the lock button, the blade shall be locking. Conversely the blade is removed. The blade should be replaced after blunt.(Figure 1)



2. Installation and removal of drill chuck

Shown to pull down the telescopic, drill chuck shaft into the host, release the telescopic drill chuck shaft is locked by the host. Conversely drill chuck shaft is removed. (Figure 2)



Figure 2

3. Drilling, sawing with component installation and removal

Aligned Drilling, sawing components with the notch which is marked on host site, directly into the host, then the attachment is installed in place. Rotate the Locking knob by the direction of the arrow, and pull the attachment out to finish the diassembling. (Figure 3,4)





Figure 3 Figure 4

4. The battery assembly's installing and disassembling

Take off the battery cage,put on the disinfection channel pull the battery into the handle,then take off the disinfection channel,put on the battery cage.Until the surgery is completed, remove the battery.(Figs. 4 and 5)

Note: Don't drop the battery to the ground, avoid damaging it.





Figure 5

Figure 6

5. Operating explanation for charging and battery:

The charger is not the medical instrument, during the charging period, the battery and the main unit is separate, the main unit can not be used. Outside the operating room Plug the AC adapter, charging indicator green light. As shown in Figure 5 Hold the battery with metal pull the pins seat into the ring to focus on the charger, the charging indicator light changes from green to red light to show charging starts, about three hours, the red light changes back to greento show charging is complete. The battery can not be used immediately after charging, wait for the battery cool then put it to the disinfecting glove and can use it in the operating room. The charged battery can be used on full load till 8 minutes.

If the battery will not be used for long time, you should charge the battery timely (15 days) to confirm the life time of the battery.

Testing the power capacity, connect the charger to the power supply, insert the socket on the battery to the charger, the LED turn to green mean the capacity is full, otherwise mean the capacity is not full, should charge it again or replace the battery. Normally, the battery can be charged and discharged for 150 times.



Figure 7

6. On/off operation:

Press the switch, the saw and drill will run; release it then stop.

The speed of the action can be controlled by the amplitude of the pressing; small means low, big means high.

7. Change the rotating direction (for drill):

Turn the switch to the L means CW (clockwise), R means CCW(counter clockwise)

Note: The rotating direction should be turned when the drill stopped.

Attention:

- 1. Do check the drill heat jumping before the operating, if it is higher than the drill, so it can not be used. Check the drill sharp or not, if not should be modified. When the tool used to cut the object, then it should be fixed and without vibrating. If the drill head is broken, so replace it immediately.
- 2. Tightly fixing drill head and saw, fix the head should use the special key. The saw should fix too with pull it to test and avoid the accident and the instrument error.
- 3. The battery should not be disinfected on high temperature and high pressure and let it in the unit for long time. If power break occurred during the operation (main unit stop), pull out the battery immediately.
- 4. If the unit is too heat or with the abnormal sound, stop using it immediately, do not disassemble, and contact to the seller or the manufacturer, and feed back the instrument to the special factory to repair in time.
- 5. Motor rotating rate: According to the normal occasion, if the speed is too high, then will cause burning the bone, if the rate is too low means the time is too long, so the suitable speed is very important. The 300 r/min is the better choice.
- 6. Disinfecting: include suffocating, high pressure and high temperature and marinating. The main unit can be disinfected by high temperature and pressure, the battery is forbidden to use this method.
- 7. If find the unit is with the high temperature, should stop using immediately, an contact to the factory in time and mail the instrument to the factory to repair.
- 8. If any potential electromagnetic interference, when used as far as possible from sensitive equipment, and avoid sensitive equipment.
- 9. Reported waste and waste recycling in accordance with regulations, to avoid affecting the environment.
- 10. The guarantee you purchased Medical Electric Saw Drill normal use, use only approved accessories I saw only Bojin saw.

Risk analyzing and the valid measure:

- 1. Because adopt the shield measure, so can control the instrument's electromagnetic wave to the valid field. So the electromagnetic wave will not exceed the standard's field, and the other instrument also will not influence the instrument. (EMC testing report: QTK NO::065L021-IT-CE-P02V01)
- 2. Cutting tools are not on the position: Operating according to the operating manual.
- 3. Battery failure: examine the battery to the battery.
- 4. The battery is not charged: charging the battery before the operation.
- 5. The battery is not full: examine the battery full or not before the operation.

Residual risk

1. The motor rotating speed:

According to the operating condition, if the speed is too high then that will burn the bone, but if the speed is too low, the time will be too long and hard. So it is very important to choose the suitable speed. The speed should be 500 r/min, it's the good choice to process the operating.

2. Disinfecting method:

There are some methods that suffocating, high temperature & high pressure, marinate to disinfect the instrument. For the handset, use the high temperature and high pressure to disinfect according

to the hospital's provision. The battery is forbidden as high temperature and high pressure and marinating.

Accessories:

Medical electric saw drill charger1 pcsJ-AA1800Ni-MH chargeable battery1 pcsClamp:1pcs

About relative instrument's quality:

- a) Medical electric saw drill is been test strictly before leaving the factory, if has the quality problem, process the service.
- b) After purchase the product, please check all the instrument.
- c) The product guarantee is 3 years, using time is 5 years.

Attention: The battery can not be disinfected with the high temperature and high pressure.

Cleaning and Sterilization:

Attention: Battery can not be sterilized by autoclaving

- 1. Cleaning: Protection when cleaning after use follow the same way when doing sterilization, the host shell can be wiped clean by water or alcohol gauze and then put in reservation.
- 2. Sterilization: This product must be disinfected before using, and it only can be used after inspection.
- 3. Recommendation for the sterilization methods: Rapid pressure steam sterilization(132°C)need shortest disinfection time

| Categories Items | Disinfection | Time |
|----------------------------|----------------|------------|
| | Bottom Exhaust | Pre-vacuum |
| Without holes items | 3min | 3min |
| Perforated items | 10min | 4min |
| Without holes + perforated | 10min | 4min |
| items | | |

Rapid pressure steam sterilization method may not include dry procedure. Pollution during transportation should be avoided. It should be used within four hours. It can't be kept in reserve.

Attention: The above recommended sterilization method is the most safety and reliable. But the time and temperature be strictly control within the range, otherwise the host will immediately necrosis!

The charger and battery can not be disinfected.

We suggest that use the formalin suffocating method that widely used in mostly hospital. With the cankerous, but it will not damage the main unit immediately, so the steam is less or disinfected by ethylene oxide, then there will be no steam and no causticity, then that is the best disinfecting method.

Acceptance: a) The instrument has not the parts that can be repaired by the non professional person, if it error, please contact to the service department.

If you need the reference about the saw drill, please mail to us.

Technical Specifications

Hand Piece BJ4200

Description of Function: The Battery Operated Drill system is a battery driven power system with a range of attachment and accessories for use in general traumatology, including drilling, sawing, inserting/removing K-Wires.

Electric Hand Piece (Battery operated)

Power: $\geq 100 \text{ W}$

Weight: $\leq 950 \text{ g}$

Sterilization method: Autoclavable 135°

Adjustable speed: 0 - 1100 rpm

Noice: $\leq 70 \text{ db}$

Battery & Attachment blocking mechanism

Quick Coupling Attachments

Increasing temperature while working: ≤ 20°C

Forward and Reverse switch with safe mode

Pistol grip handpiece, ergonormic design

Battery BJ4001

Insert/detachment method: telescopic, easily

Run time with fully charged battery: ≥ 30 min

Ni-Mh rechargeable battery, 14.4V / 1800mAh

Non-memory

Non-autoclavaible

Shield to protect battery from the housing

Battery Charger BJ1002-4

Simultaneosly charged batteries: 4 batteries

Light charging indicator

Input Voltage: 110-250V, 50/60Hz.

The output voltage: 17.5*4 (this is for four charger).

Output Current: 700mAh

Sagittal Saw Attachment BJ4201

360° Rotating: Up, down, left and right

Adjustable speed: 0 - 15000 cycles/min

Sterilization method: Autoclavable 135°

Tool less blade mounting

Blade arc of excursion: 5 degree

Drill Attachment BJ4201

Adjustable speed: 0 - 1100 rpm

Drill Bit range: 0.5 - 7.4 mm

Sterilization method: Autoclavable 135°

Output power: 3 Nm

Forward & Reverse mode

Drill Attachment BJ4202SAO

Adjustable speed: 0 - 1100 rpm

Sterilization method: Autoclavable 135°

Output power: 3 Nm

AO Quick coupling tool

Forward & Reverse mode

Drill Attachment BJ4203B

Adjustable speed: 0 - 800 rpm

Sterilization method: Autoclavable 135°

Output power: 3 Nm

Forward & Reverse mode

Dual mode function: drilling and K-Wire inserting

Sagittal Saw Attachment BJ4201

360° Rotating: Up, down, left and right

Adjustable speed: 0 - 15000 cycles/min

Sterilization method: Autoclavable 135°

Tool less blade mounting

Blade arc of excursion: 5 degree

Reciprocating Saw Attachment BJ4209

Adjustable speed: 0 - 15000 cycles/min

Sterilization method: Autoclavable 135°

Tool less blade mounting

Acetabulum Reaming Drill Attachment BJ4207B

Adjustable speed: 0 - 300 rpm

Sterilization method: Autoclavable 135°

Forward & Reverse mode

Output power (to 250 rpm): 8 Nm

K-Wire Drill Attachment BJ4213A

K-Wire diameter range: Ø 0.8mm - Ø 2.0mm

Adjustable speed: 0 - 1100 rpm

Forward & Reverse mode

Sterilization method: Autoclavable 135°

K-Wire Drill Attachment BJ4213B

K-Wire diameter range: Ø 2.0mm - Ø 3.0mm

Adjustable speed: 0 - 1100 rpm

Forward & Reverse mode

Sterilization method: Autoclavable 135°

Optional Attachments

High speed drill attachment BJ4202

High speed drill attachment BJ4202SAO

Cannulated drill attachment BJ4203D

Acetabulum reamer attachment BJ4207B

Accessories

European power cable

Jacob Chuck Key BJ1005

Sterilization container BJXDH4200

Sagital blade standard set: BJ90221.0A / BJ90141.0A / BJ90251.0A

Reciprocating blade standard set: WF70131.0B / 2WF70131.0B

Drill Bit standard set: BJZC-1.5-35-115 / BJZC-2.0-35-115 / BJZC-2.5-35-115 / BJZC-2.7-50-115 / BJZC-3.0-50-115 / BJZC-3.2-50-115 / BJZC-3.5-50-115 / BJZC-4.0-50-115 / BJZC-4.5-50-115

Other

Warranty: Handpiece, Attachments & Battery Charger: 2 years warranty.

Accessories: 6 month.

Transportation and storage condition:

1) Temperature range: $-10^{\circ}\text{C} \sim +40^{\circ}\text{C}$

2) Relative humidity range: ≤90%

3) Air pressure: 500hPa~1060hPa

Equipment running condition:

1) Temperature range: 5°C~+40°C

2) Relative humidity range: ≤70%

3) Air pressure: 860hPa~1060hPa

4) Charger power supplier: 220V±22V; 50Hz±1Hz

Saw drill power supplier (DC): 14.4V±10%